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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924				
EXAMINER				
PEFFLEY, MICHAEL F				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/752,135

Applicant(s)

FRANCISCHELLI ET AL.

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-15 is/are allowed.
- 6) ☒ Claim(s) 1-12 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/6/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicant's amendments and comments, received December 18, 2007, have been fully considered by the examiner. In particular, applicant's arguments with respect to the Oath/Declaration are persuasive and the objection has been withdrawn. The following is a complete response to the December 18, 2007 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 21, 22, 25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al (5,443,463) in view of the teaching of Taylor (6,113,592).

Stern et al discloses a system comprising an ablation apparatus (10) having first and second jaws (20,30). Energy is delivered to a first side of tissue via electrodes (21), and an array of temperature sensors (31) in close proximity are provided on the other jaw to sense temperature on the opposite side of tissue (Figure 1A). An output device (i.e. computer 114) is used to control the output of RF energy in response to the sensed temperature. In as much as applicant's specification teaches that temperature provides an indication of lesion transmural, the examiner maintains that the Stern et al system is inherently adapted to provide an indication of transmural of the lesion (i.e. coagulation zone) since it is monitoring tissue temperature. As seen in Figures 2B and 6, the sensors are provided in the form of a grid. Stern et al fail to specifically disclose that the output device provides for continuous indication of lesion transmural.

Taylor discloses another apparatus for performing transmural lesions, and specifically disclose using temperature monitoring to inform the user of the progress of

the lesion. In particular, Taylor discloses a computer (250) having a display (251) for continuously showing the temperature progress as an indication of lesion transmuralty. The display may be used to show data, images or temperature curves indicative of the progression of the lesion.

To have provided the Stern et al system, which includes temperature sensors and a computer for analyzing and controlling operating parameters, with a means to provide a continuous display of the data to inform the user of the transmuralty of the lesion being created would have been an obvious consideration for one of ordinary skill in the art since Taylor teach that it is known to use a display means to provide a continuous indication of lesion transmuralty.

Claims 1-4, 6-9, 12, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al (5,443,463) in view of the teachings of Nagai et al (5,172,949) and Taylor (6,113,592).

Stern et al has been addressed previously. While Stern et al teaches of providing energy to one side of tissue and monitoring temperature on an opposite side of tissue, there is no specific teaching of using suction to hold the tissue on the working surface as recited in claim 1. Also, there is no specific disclosure of an output device that provides continuous indication of the transmuralty of the lesion.

Nagai et al, as addressed in the previous Office action, discloses that it is known to provide a combination suction and temperature sensing element to hold a working surface in contact with the device for monitoring temperature.

And as addressed above, Taylor discloses another apparatus for performing transmural lesions, and specifically disclose using temperature monitoring to inform the user of the progress of the lesion. In particular, Taylor discloses a computer (250) having a display (251) for continuously showing the temperature progress as an indication of lesion transmural. The display may be used to show data, images or temperature curves indicative of the progression of the lesion.

To have provided the Stern et al temperature monitoring jaw with a suction source associated with the temperature sensors for holding tissue during treatment and tissue temperature monitoring would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Nagai et al. To have further provided the Stern et al system with a means to provide continuous display of the data to inform the user of lesion transmural would have been an obvious modification for the skilled artisan in view of the teaching of Taylor.

Claims 5, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('463), Taylor ('592) and Nagai et al ('949) as applied to claims 1 and 4 above, and further in view of Chinn (5,647,868).

The combination of the Stern et al device with the Nagai et al and Taylor teachings has been addressed. While Stern et al disclose a computer system for controlling and displaying data, there is no specific teaching that a representation of the device is used to indicate measured parameters such as temperature (i.e. lesion transmural).

Chinn discloses an analogous RF treatment system that uses temperature sensing to control RF output. In particular, Chinn teaches that it is known to provide a display that includes a visual representation of the device to show sensed and performance output parameters during a surgical procedure. This allows the user to visually acquire data of the system during the procedure.

To have provided the Stern et al device, as modified by the teachings of Nagai et al and Taylor, with a virtual display to provide a visual representation of the system and working parameters such as temperature would have been an obvious modification for one of ordinary skill in the art since Chinn teach it is known to use such a display to assist in analogous surgical procedures.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('463), Taylor ('592) and Nagai et al ('949) as applied to claim 1 above, and further in view of Hoffman (4,682,605).

Stern et al fail to disclose the use of liquid crystals and/or temperature sensing chemicals to monitor temperature. The examiner maintains that the use of any well-known temperature sensing mechanism in the Stern et al device would be an obvious substitution.

To that end, Hoffman et al disclose that it is old and well-known to use temperature sensing devices such as liquid crystals and temperature sensing chemicals to provide detailed temperature mapping of tissue.

To have provided the Stern et al device, as modified by the teachings of Nagai et al and Taylor, with liquid crystals or temperature sensing chemicals as the temperature sensing grid on the second jaw of the device would have been an obvious modification for one of ordinary skill in the art since Hoffman fairly teaches that it is known to use such means for tissue temperature monitoring.

Claims 23, 24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('463) and Taylor ('592) in view of the teaching of Chinn ('868).

Again, Taylor discloses a computer system for controlling and displaying data that may be combined with the Stern et al system, but there is no specific teaching that a representation of the device is used to indicate measured parameters such as temperature.

Chinn discloses an analogous RF treatment system that uses temperature sensing to control RF output. In particular, Chinn teaches that it is known to provide a display that includes a visual representation of the device to show sensed and performance output parameters during a surgical procedure. This allows the user to visually acquire data of the system during the procedure.

To have provided the Stern et al device, as modified by the teaching of Taylor, with a virtual display to provide a visual representation of the system and working parameters such as temperature would have been an obvious modification for one of

ordinary skill in the art since Chinn teach it is known to use such a display to assist in analogous surgical procedures.

Allowable Subject Matter

Claims 13-15 are allowable over the prior art of record.

Response to Arguments

Applicant's arguments with respect to claims 1-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner
Art Unit 3739

/mp/
February 8, 2008